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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,134	03/16/2007	Nigel Tooke	068490-079788	9448
26288	7590	09/17/2010		
Aibihns.Zacco AB P.O. Box 5581 Valhallavagen 117 STOCKHOLM, SE-114 85 SWEDEN			EXAMINER CHUNDURU, SURYAPRABHA	
			ART UNIT 1637	PAPER NUMBER
			MAIL DATE 09/17/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/562,134	TOOKE ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-6,8-12 and 14-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6,8-12 and 14-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 January 2008 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/7/10</u> .  | 6) <input type="checkbox"/> Other: _____                          |

**DETAILED ACTION**

1. Applicants' response to the office action filed on July 07, 2010 has been considered and acknowledged.

***Status of the Application***

2. Currently claims 1-6, 8-12, 14-25 are pending. Claim 7, 13, 26-34 were previously cancelled. All arguments and amendment have been fully considered and thoroughly reviewed and deemed unpersuasive for the reasons that follow. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. The action is made FINAL.

***Response to arguments:***

3. With regard to the rejection of claims 1-6, 8-12, 16, 19, 22 under 35 USC 102(e) as being anticipated by Jansson et al., Applicants' arguments were fully considered and found unpersuasive. First, Jansson et al. reference as whole, does teach use of pyrophosphate in the detection step, the cited paragraph 0019 of Jansson et al. teach release of AMP and pyrophosphate mediated by luciferase-luciferin reaction. The following paragraph 0020 further teach the conversion of AMP to ATP by a phosphate donor (pyrophosphate) (as evidenced by the PCT/FI03/00131 as cited in the paragraph 0020) by the utilization of adenylate kinase, nucleoside-diphosphate kinase and dCTP, which inherently teach that the pyrophosphate released as by product is used in detecting the ATP. In addition as stated in MPEP 2131.01 'Extra Reference or Evidence Can Be Used To Show an Inherent Characteristic of the Thing Taught by the Primary Reference is inherent'. In the present context, PCT/FI03/0031 reference cited in paragraph 0020 teaches the reaction steps for conversion of AMP into ATP that utilizes pyrophosphate released as a bi-product, which supports inherency of the reaction steps utilizing

pyrophosphate as a phosphate donor in the conversion of AMP into ATP. Second, the claims are in 'comprising' open format, and according to MPEP 2111.03, as additional elements or steps that are unrecited are within the scope of the claims. Thus the reaction steps converting AMP to ATP are within the scope of the instant claims. Third, the cited paragraph 0007 of Jansson et al. teach the detection of AMP as an indication of presence of ligation product, which is a measure for the presence or absence of the genetic element, and it is not cited as a basis for ATP or pyrophosphate production as asserted by the Applicants. Accordingly the rejection is maintained.

5. With regard to the rejection of claims 1-6, 9, 14, 16-18, 20-24 under 35 USC 102(b) as being anticipated by Shultz et al., Applicants' arguments were fully considered and found unpersuasive. First, Shultz et al. does teach detection of ATP and use of pyrophosphate in detection system because the Examiner cited paragraphs does teach said limitations. Second, as discussed above, the claims are in open 'comprising' format and thus the reaction steps converting AMP into ATP that utilize phosphate donor from pyrophosphate that is released as a by product are within the scope of the instant claims. Third, the cited portion col. 41, line 42-56 of Shultz et al. does teach detection of ATP, which inherently utilizes a phosphate from pyrophosphate to convert AMP into ATP. Accordingly the rejection is maintained.

6. With regard to the rejection of claims 15, and 25 under 35 USC 103(a) as being obvious over Jansson et al. in view of Schalling et al. , Applicants' arguments were fully considered and found unpersuasive. As discussed above Jansson et al. does teach the method and as discussed in the rejection it would have been obvious to modify the method with the teachings of Schalling et al. With regard to no teaching or suggestion to combine the references, it is noted obviousness can only be established by combining or modifying the teachings of the prior art to produce the

claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, specific motivation is provided in the rejection, which states that An ordinary person skilled in the art would have motivated to combine the references because the ordinary practitioner would have a reasonable expectation of success that the combination would result in improving the specificity by reducing the non-specific and unintended products because Schalling et al. explicitly taught that the use of repeat sequences and normalization of signal to achieve specific target detection (see col. 2, line 20-34, col. 6, line 1-10) and such a modification of the method is considered obvious over the cited prior art.

### ***Conclusion***

No claims are allowable.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Suryaprabha Chunduru/

Primary Examiner, Art Unit 1637